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ABSTRACT

The ethical treatment of human participants in medical research has been a focus of discussion for centuries. Less talked about, unfortunately, is how participants of social science research, especially of the kind of research found in educational settings, are protected from unethical procedures or investigators. Title 45 of the U.S. Code of Federal Regulations, Part 46, contains provisions generally allowing educational research to be exempt from Institutional Review Board review process. Recent legislative movements, together with rapidly changing technologies and research approaches, are forcing a reconsideration of this traditional exemption. This paper summarizes the federal regulations under which educational researchers are expected to operate. Recent legislative imperatives are reviewed, and the role of the Institutional Review Board is discussed. New questions concerning the ethical treatment of human subjects in educational research are raised, and suggestions for how each institution might address these challenges to the research process are presented. Attachments include "The Belmont Report," a report on ethical principles for the protection of human subjects from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Title 45 of the Code of Federal Regulations, and selected portions of federal acts and commentary. (Contains 17 references.) (Author/SLD)

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# Educational Research, Research Ethics and Federal Policy: An Update

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Abstract

The ethical treatments of human participants in medical research has been a focus of discussion for centuries. Less talked about, unfortunately, is how participants of social science research, especially of the kind of research typically found in educational settings, are protected from unethical procedures or investigators. Title 45 of the U.S. Code of Federal Regulations, Part 46, contains provisions allowing educational research to generally be exempt from Institutional Review Board review process. Recent legislative movements, together with rapidly changing technologies, are forcing a reconsideration of this traditional exemption. This paper summarizes the federal regulations under which educational researchers are expected to operate. Recent legislative imperatives are reviewed, and the role of the Institutional Review Board (IRB) is discussed. New questions concerning the ethical treatment of human subjects in educational research are raised, and suggestions for how each institutions might address these challenges to the research process are presented.

Educational Research, Research Ethics, and Federal Policy: An Update

In response to a number of research experiments that had mistreated research subjects the National Research Act, enacted on July 12th of 1974, established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges of this commission was to develop ethical principles and guidelines for researchers to follow in the conduct of research involving human subjects. One of their key reports, know as The Belmont Report (Appendix A), became the base work of many guidelines that followed.

The Public Health Service Act (as amended in 1985 by P.L. 99-158 and in 1993 by P.L. 103-43) called for the creation of regulations that would establish Institutional Review Boards (IRBs). Through the Department of Health and Human Services these laws were codified into the Code of Federal Regulations Title 45: Public Welfare, Part 46: Protection of Human Subjects (Appendix B). In the intervening years over 50 federal agencies, including the National Institutes of Health and the Office for Protection from Research Risks, have agreed to have research conducted for or sponsored by their agencies adhere to the rules stated in 45CFR46. Some agencies, like the Food and Drug Administration, have created additional regulations that apply to particulars that agency must address (such as the development and approval of new drugs, medical devices, and procedures).

A key facet of this legislation, and the ensuing regulation, was the requirement for institutions conducting federally funded research to have and maintain Institutional Review Boards. The IRBs were given the authority to "review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy" (45 CFR § 46.109). IRBs were specifically to: assess the risks associated with a research effort in relationship to the benefits to be gained, insure for an equitable selection of subjects, and determine that informed consent, including the informed assent of minors and those unable to grant informed consent, of the human participants was to be obtained and appropriately documented. During the mid- to late-1980s most institutions of higher learning established IRBs and began applying the rules of 45CFR46 to the research conducted on their campus or by their faculty and/or staff.

Recognizing that certain types of research typically posed little risk to the subjects, and were already commonplace in our society, the regulations established six categories of research that were to be "exempt from this policy". Included in this exemption were the following paragraphs that are of particular interest to educational researchers:

> (1) Research conducted is established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

> (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
>
> > (i) information obtained is recorded in such a manner than human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
>
> (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observations of public behavior that is not exempt under paragraph (b)(2) of this section if:
>
> > (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (45 CFR §46.101)

Although these components of the regulation would seem to make most, if not all, educational research exempt from the IRB process that is rarely the case. Additional sections in the regulation call for specific protection to be afforded to children, especially those of diminished capacity (Subpart D, 45 CFR §46.401 through .409). Other sections require a greater degree of IRB review of proposed research if the investigator is to record data using an audio recorder (an expedited review process, 45 CFR §46.110). Further, questions have arisen through the research and educational communities concerning several critical terms in the aforementioned sections. For example, what is a "commonly accepted educational setting", and when is a practice a "normal educational practice"?

For the past two decades educational researchers have been trying to find means to work within these scope of these regulations. Grotberg in 1979 described the building resistance by educational researchers to complying with the new regulations. In 1983, Lyons wrote to rural educators about these regulations, giving suggestions for how to completed IRB proposal forms. The intersection of local practice and custom, federal and state regulation, and a desire on the parts of researchers and practitioners alike to advance the field of knowledge while acting in a professional and ethical manner, seem to have created more questions than answers.

These issues embodied by the principles of The Belmont Report and 45CFR46 are still not universally decided, nor even well understood, by many educational researchers and practitioners alike (Sieber and Baluyot, 1992). Recent focus by federal legislators has further heightened the attention paid to this topic.

The New Legislation

On March 31, 1994 Title 20, United States Code, part 1232h, was amended to provide additional protection for pupil rights (Appendix C). Generally known as the "Grassley Amendment", after Senator Charles E. Grassley (R-IA), these provisions require the prior written consent of parents for research conducted with children in schools that was funded by the Department of Education. Any "survey, analysis, or evaluation" that asked for information in seven specific areas of concern would be covered by this policy. Further, all "instructional materials, including teacher's manuals, films, tapes, or other supplementary materials which will be used in connection with any survey ... shall be available for inspection by the parents or guardians of the children."

Researchers not involved in Department of Education funded studies probably have not heard much about this new law. Regulations being proposed by the Department to implement the new law would narrow the application of the regulation only to surveys and studies given to students in elementary and secondary education, not in higher education (Human Research Report, 1995). Apparently these proposed regulations have angered the Senator, a spokesman for whom was quoted as saying "the effect of the regulations is to gut the intent of the amendment".

Since that time new legislation has been passed by the House of Representatives and is currently under consideration in the Senate. Known as H.R. 1271, the Family Privacy Protection Act of 1995, this bill seeks to make provisions similar to those already enacted apply to all research, whether funded by the Department of Education or not (Appendix D). In addition to requiring written consent from parents prior to a child participating in a survey or interview, this new legislation has the potential for eliminating all forms of passive consent (for example, assuming that consent is given when a consent giver fails to return a document denying consent). Further, this new regulation would apply if the program/school received any kind of federal funding at all.

> In effect, what this means for parents is that they no longer have to prove that the specific activity that they find offensive is federally funded. They no longer have to show that it is a research or experimentation program or that it is a psychiatric or psychological test with the primary purpose of revealing private information. They must simply show that the survey, analysis, or evaluation revealed private information, that it was in a federally funded program, and that their consent was not obtained. This is much easier for a parent to demonstrate and will thus provide wider protection for parents and students. (Human Research Report, 1995, p. 6)

How will researchers be able to conduct survey, observation, and interview kinds of research on children dealing with sensitive areas if parents must consent in writing prior to each interaction? In addition to the added time and increased cost required to obtain such written consents researchers might find their subject pools reduced in number and/or skewed or restricted. This might be especially bothersome in studies that deal with sexual behaviors/AIDS,

child abuse or neglect, and the like. Of additional concern is the feeling that this legislation would mandate processes outside of the IRB process. Rather than allowing a researcher to present the case for their research to an impartial panel of local experts and citizens all such research would be subject to the same requirements, whether they are in fact useful or detrimental.

H.R. 1271 is currently under consideration by the Senate (see Appendix E for the time line of legislative actions to date). Many notable organizations, including the American Psychological Association (see Appendix F), have come out firmly against the bill, citing numerous reasons for their opposition. Perhaps the most cogent arguments have been made by Felice Levine (1995), in her testimony before the Senate Committee on Governmental Affairs considering the Family Privacy Protection Act (Appendix G is a transcript of her testimony). She points out the added cost, reduced research opportunities, and potential decrease in the validity of research findings if H.R. 1271 is adopted as currently written. Her most important point, however, is that a system already exists whereby human subjects are protected from research risks -- the IRBs.

## Issues for Educational Researchers and Institutional Review Boards

Social science research, with educational research in particular, poses a unique set of considerations for both the researcher attempting to conduct the research and the institutional review board attempting to provide adequate protections for the human subjects that are involved. Questions arise that are not clearly addressed in existing regulation. The standards of communities, which vary from place to place and time to time, also must be considered. The following issues are critical for researchers and IRBs both to consider.

### What does it mean to be "exempt"?

One of the first issues a new IRB faces is what it means to be "exempt" under 45 CFR 46 (Weinberger, 1981; Howe and Dougherty, 1993). It was clear that the regulations were crafted so as to not create an undue burden on everyday processes, especially those found in educational settings. By the same token the regulation contains ambiguities and conflicts, especially when utilizing children or other vulnerable populations. Should a principal investigator be allowed to decide if their own research is exempt from review? Further, what is the normal practice is a given educational setting?

Unfortunately, no clear or single answers exist to any of these questions. Researchers and IRBs across the country have interpreted the regulations differently on each of the issues, crafting specific policies and procedures tailored to the needs of their institution and local community. To a large degree this is how the regulations were intended to operate. There is a convincing argument, however, for certain constants that should apply across all cases.

It would not be unreasonable to assume that a principal investigator, and his or her co-investigators, is more in touch with a given research effort than any other person. The investigator understands the background literature on the topic, has considered numerous means for

investigation, and is oftentimes financially and viscerally committed to the satisfactory conclusion of the research. This closeness has been shown to create a bias when dealing with research subjects, especially when the investigator is aware of the conditions a given subjects will be exposed to (treatment or control). Since experimenter bias is such a powerful force in swaying the results of a study many researchers will employ the use of a "blind", whereby those investigators in direct contact with the subjects are oftentimes ignorant of the specific treatment given to a subject. In this way all subjects will be afforded the same treatment or, if there is variation, at least it will not be attributable to the researcher's knowledge of the research conditions.

The same considerations arise when one is asked to determine whether one's own research should be exempt from a given policy. Although the investigator is the most familiar with the research effort he or she is also the most vested into it. The only reasonable course of action that removes the potential for bias requires an outside person or group, such as an IRB, to act as the impartial reviewer. Such an external review process, in addition to removing any potential suggestion of impropriety, insures that the researcher and his or her subjects are both protected from any accidental oversights or omissions that sometimes occur. The burden of having an outside person or group review all research to determine if, in fact, the research qualifies for an exemption as outlined is the federal guidelines does add another step to the process of systematic investigation. The benefit gained is well worth that effort.

Deciding what is a normal practice in a given educational setting can be a difficult task. What is common and accepted at one place, or at a certain time, may not be common nor accepted somewhere or somewhen else. On this point we must rely heavily upon the integrity of each researcher. As they are the ones most familiar with the research subjects they must come to understand what is typical and expected for that group. Local customs, norms, and conventions must be considered in each and every case, a process which could add a burden to studies covering larger geographic areas.

If the prior suggestion of an external review for all research is implemented the researcher is afforded an opportunity to demonstrate, in a proposal submitted for review, that their study is identical or closely similar to everyday occurrences. Such a demonstration within the proposal documentation would go a long way to bolstering a claim that a given research project should be considered as exempt from further review.

Consent and assent

In the past it was sufficient for a researcher to secure the consent of participating research subjects, or the parent or legal guardian if the subject was a minor. This process of consent had developed from the legal traditions, including such notions as: the transferral of all relevant information, comprehension on the part of the consent giver, and agreement to participate free of undue pressure or coercion. Also a part was the idea that the subject was legally entitled to give their consent. Individuals who were incarcerated, of diminished capacity, or not yet of the age of

majority could not give legal consent. Instead another person, or the state acting as their guardian, was empowered to consider whether or not to consent on behalf of the potential subject.

It was clear, however, that even though an individual might not be able to give a legally appropriate form of consent the ethical treatment of each potential research subject requires each person's assent to the research process. Thus, a notion of assent was born whereby most, if not all, research subjects were to be solicited for their active assent to their research participation. In this way it was hoped to protect understanding minors and other individuals from exposure to conditions they did not want even though another had provided legal consent for their participation. For children, especially those exposed to school-based research, this would afford an extra means of protection against overexposure to research, forced participation, and misused research findings (Grotberg, 1979).

Unfortunately, recent research has shown that the dual intents of legal consent and subject assent are not always being met. In many cases the forms and scripts used to solicit consent and/or assent are at a higher reading level than appropriate for the intended subjects (Ogloff and Otto, 1991). This results in many minors not understanding the nature of the research, their role in the effort, or the anticipated risks and benefits. Worse, many children were found to not understand that they could discontinue their participation after they had started if they so desired (Nannis, 1987; Abramovich, Freedman, Henry, and Van Brunschot, 1995). Thus, while the letter of the regulations appears to be satisfied it has been shown that the spirit of the ethical protection of minors subjects is often not.

The implication for educational researchers should be clear. Obtaining consent from the legal parent or guardian must be considered as only the first step in securing the participation of a minor subject. Securing the assent of the minor is the second, critical step. This stage must further involve substantive provisions to insure that the minor understands as fully as is possible the research effort, their role, the risks and benefits and, most importantly, their right not to participate at all and to withdraw at any time (Sanford, 1993). Research has shown repeatedly that minors, to a very young age and even with learning and behavior problems, have this capacity understand (Adelman, Lusk, Alvarez, and Acosta, 1985). Educational researchers, who so often interact with minor subjects in the course of research, must make that extra effort to insure that their assent is clearly and capably obtained.

<u>When is it teaching and when is it research?</u>

Another issue that frequently confronts university-based IRBs involves research conducted in conjunction with a class. Variations on this theme range from studies conducted within the confines of the classroom solely to used for classroom exercises to studies where the students, acting as researchers, collect data in the field with the hope of writing a paper and presenting their findings. A quick read of the regulation might lead one to believe that, unless the study were to contribute to "generalizable knowledge" (as stated in the regulation), it was not to be considered research. A common definition for generalizable knowledge would include the results of a

research effort being published as a paper in a journal or presented at a meeting. If data is to be collected but the intent is not to publish or present, is the activity to be considered research?

Rather than considering what might be done with the product of the research effort (the paper or the presentation) one must instead consider the research activity itself. The intention of the researcher may be, initially, not to publish or present his or her data; however, once it has been collected that data might look better than initially intended and be suitable for such purposes. On the other hand a researcher might have every intention of publishing or presenting findings but, due to unsympathetic reviewers or editors be unable to find an appropriate outlet for their work. The end product of the research effort is, oftentimes, not under the direct control of the principal investigator.

The research activities, however, are under the investigator's direct control. Whether that investigator is a student or a teacher, in a classroom or in the field, they have a responsibility to behave in an ethical and professional manner. At almost every educational institution at every level procedures exist to insure the fair treatment of students by faculty in classes and other academic ventures. Appropriate codes of conduct can be found for both faculty and students, and mechanisms exist for investigating and adjudicating complaints of faculty against students and students against faculty. Oftentimes the syllabus and class handouts serve as a quasi-contract between a faculty and the students enrolled in a class as to what activities are expected, and what grades will be awarded, in a particular class. Within the confines of a class, then, there appears to be adequate provisions for protecting the rights of all individuals involved. Whether it happens within the physical classroom or outside both faculty and students have an <u>academic</u> responsibility and obligation to behave in certain ways.

Such protections, however, are not found when a faculty or student actively encounters individuals not enrolled in the class. An outsider is most likely unfamiliar with the requirements of the course, the particular assignment being accomplished, or the protections available through academic channels. Further, if the activity is a research activity -- one where an systematic observation or interaction is made of human subjects in a naturally occurring or purposefully manipulated condition -- those human subjects may be totally unaware of their participation.

In this context, then, teaching ought to be described as an activity that occurs between and among students and teachers. If the activity is to be a research activity (as defined above) but is to take place solely among the students and teachers as part of a recognized instructional process, where the students and teachers all know of the design and purpose (such as through a syllabus or handout), the activity may validly be considered <u>not</u> as research for IRB purposes. If, on the other hand, the activity is to involve individuals who are not students or faculty participating in the course, or is to involve activities where the students and/or teachers are unaware of their participation (such as a faculty systematically studying their students' responses to manipulated conditions), the activity should be considered research and subject to IRB review and approval.

What about, then, activities like student teaching and corporate internships? Although these activities involve individuals beyond the students and teachers there is a clear sense and understanding by all involved that such activities are for the training of the students and not for systematic investigation or research. In these cases the IRB encourages clear communication of purposes and intents among all participating individuals so that everyone understands the nature and extent of the activity's interactions. These activities, however, are not research and need not be reviewed by an IRB. One final note: on occasion an individual involved in a student teaching practicum or corporate internship wants to conduct research as a part of their other experiences. While the thrust of the primary activity is not research that additional activity would be and, therefore, would require a proposal submission to the IRB.

What about the use of audio, video and computer technologies?

The use of new technologies is posing a set of questions for which there are no clear or definitive answers. Computer, audio, and video recording technologies may be used as an integral part of a research project or may just serve as an ancillary means of recording data. While the current regulations allow for an expedited review process for studies using audio recordings nothing is stated about video or computer technologies.

It should be apparent that it is not the technology that is necessarily of interest but rather the degree to which an human subject surrenders their privacy, their right to confidentiality (Linowes, 1979). Research processes that involve technologies likely to reduce privacy need be given a more stringent review than those less likely to intrude upon personal space and information. Thus, studies which involve only handwritten notes taken by the researcher without reference to an individual's name or other identification should generally qualify for exempt status. Studies that use an audio recorder where a person's voice might be identified, or a computer record where an individual's name or other identifier is stated, may qualify for an expedited review process if appropriate care is taken to guard teach individual's identity and the confidentiality of the individual data presented. Those studies using procedures and/or technologies where the identification of an individual subject is relatively easy, such as through the use of a video recording or electronic mail, must be afforded a more stringent review.

This issues is especially important when considering the latest research being conducted over the Internet. A common belief a few years ago was that computers, electronic mail, and the information sent across Internet were inviolate. Successful and well publicized accounts of computer crime, the reading of e-mail by institutional superiors, and the snooping of Internet-transmitted data have completely shattered this myth. No one should assume that their network interactions are not being viewed by others unless specific steps have been taken to strongly encrypt the information being transmitted.

This is not to say that these types of data collection methodologies and technologies make the studies more risky for the human participants. The actual degree of risk might, in fact, be very small. Rather, it is the methodology and technology that could be used to ends not well

understood by the human subject. An IRB should require the researcher, when using such methods and technologies, to discuss how the researcher will maintain the privacy of the individual and the confidentiality of the data that is collected. If, for example, a video tape record is to be kept and shown by the researcher as part of a presentation from the study the researcher must make that intent clearly known to the subjects as part of the informed consent process. If research is to be conducted through e-mail communications over the Internet subjects must be warned that their communications may be intercepted and read by other parties. The increased level of review by the IRB insure that these considerations and protections are made.

## Summary

Educational researchers have long enjoyed a unique place within the construct of human subject protection in social science research. It had been assumed by many that if the research effort involved only normal educational practices and took place within a school it could be exempt from any kind of review regulation. Recent attention by legislators to the kinds of research that actually takes place in schools, and the difficulty of clearly defining normal educational practices, have focused increased attention on educational research. New technologies, especially the explosive increased use of video cameras and computer networks, are posing new and difficult issues for all researchers. Educational researchers and institutions alike must readdress these issues in a positive, proactive way. Rather than waiting for a revised federal regulation to describe how and when research ought to be accomplished the research community should take steps to address these issues and find workable alternatives and solutions. The mechanism of impartial review established into the IRBs provides a vehicle for such action. It is up to the IRBs, institutions and researchers to make it happen.

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OPRR Reports

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# The Belmont Report

**Ethical Principles and Guidelines for the Protection of Human Subjects of Research**

## The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

**April 18, 1979**

**DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

**Office of the Secretary**

**Protection of Human Subjects**

**Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**

**AGENCY:** Department of Health, Education, and Welfare.

**ACTION:** Notice of Report for Public Comment.

**SUMMARY:** On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the **Federal Register,** and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78–0013 and No. (OS) 78–0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

**National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**

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Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.

Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.

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**Belmont Report**

*Ethical Principles and Guidelines for Research Involving Human Subjects*

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes[1] intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

**A. Boundaries Between Practice and Research**

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.[2] By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.[3]

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

**B. Basic Ethical Principles**

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of

[1] Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

[2] Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of pratice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

[3] Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

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human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect for persons, beneficence and justice.

1. *Respect for Persons.*—Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequences. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. *Beneficence.*—Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful, and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children—even when individual research subjects are not direct beneficiaries. Research also makes is possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that pres-

ents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. *Justice.*—Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

### C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. *Informed Consent.*—Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

*Information.* Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the

extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

*Comprehension.* The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited—for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disabled patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

*Voluntariness.* An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

*2. Assessment of Risks and Benefits.*—The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

*The Nature and Scope of Risks and Benefits.* The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons.

The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk benefit assessments are concerned with the probabilities and magnitudes of possible harms and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

*The Systematic Assessment of Risks and Benefits.* It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research shoud reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. (iii) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject—or, in some rare cases, to the manifest voluntariness of the participation). (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

*3. Selection of Subjects.*—Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.



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Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

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# OPRR Reports

NIH PHS HHS

# PROTECTION OF HUMAN SUBJECTS

TITLE 45
CODE OF FEDERAL REGULATIONS
PART 46

REVISED JUNE 18, 1991

REPRINTED MARCH 15, 1994

# THE PUBLIC HEALTH SERVICE ACT
## AS AMENDED BY
## THE HEALTH RESEARCH EXTENSION ACT OF 1985
## PUBLIC LAW 99-158
## NOVEMBER 20, 1985

*"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM*

*"SEC. 491. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.*

*"(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.*

*"(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.*

*"FETAL RESEARCH*

*"SEC. 498. (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—*

*"(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or*

*"(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.*

*"(b) In administering the regulations for the protection of human research subjects which—*

*"(1) apply to research conducted or supported by the Secretary;*

*"(2) involve living human fetuses in utero; and*

*"(3) are published in Section 46.208 of Part 46 of Title 45 of the Code of Federal Regulations;*

*or any successor to such regulations, the Secretary shall require that the risk standard (published in Section 46.102(g) of such Part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.*

*NOTE: Section 46.102(g) becomes Section 46.102(i) in Title 45 CFR Part 46 as revised on June 18, 1991.*

**THE PUBLIC HEALTH SERVICE ACT**

AS AMENDED BY

THE NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT

OF 1993

PUBLIC LAW 103-43

JUNE 10, 1993

*"CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH*

*"SEC. 492A. (a) REVIEW AS PRECONDITION TO RESEARCH.—*

*"(1) PROTECTION OF HUMAN RESEARCH SUBJECTS.—*

*"(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 491(a) by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.*

*"(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.*

**THE CODE OF FEDERAL REGULATIONS**
**TITLE 45 CFR PART 46**
**IMPLEMENTS THESE AMENDMENTS**
**TO THE PUBLIC HEALTH SERVICE ACT**



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## PART 46—PROTECTION OF HUMAN SUBJECTS

**Subpart A—Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)**

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46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
46.408 Requirements for permission by parents or guardians and for assent by children.
46.409 Wards.

**Authority**: 5 U.S.C. 301; Sec. 474(a), 88 Stat. 352 (42 U.S.C. 2891-3(a))

**Note:** As revised, Subpart A of the DHHS regulations incorporates the Common Rule (Federal Policy) for the Protection of Human Subjects (56 FR 28003). Subpart D of the HHS regulations has been amended at Section 46.401(b) to reference the revised Subpart A.

**The Common Rule (Federal Policy) is also codified at**

**7 CFR Part 1c Department of Agriculture**

**10 CFR Part 745 Department of Energy**

**14 CFR Part 1230 National Aeronautics and Space Administration**

**15 CFR Part 27 Department of Commerce**

**16 CFR Part 1028 Consumer Product Safety Commission**

**22 CFR Part 225 International Development Cooperation Agency, Agency for International Development**

**24 CFR Part 60 Department of Housing and Urban Development**

**28 CFR Part 46 Department of Justice**

**32 CFR Part 219 Department of Defense**

**34 CFR Part 97 Department of Education**

**38 CFR Part 16 Department of Veterans Affairs**

**40 CFR Part 26 Environmental Protection Agency**

**45 CFR Part 690 National Science Foundation**

**49 CFR Part 11 Department of Transportation**

## PART 46—PROTECTION OF HUMAN SUBJECTS

## Subpart A—Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

Source: 56 FR 28003, June 18, 1991.

### § 46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative

standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal Department or Agency, whether or not it is regulated as defined in § 46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal Department or Agency but is subject to regulation as defined in § 46.102(e) must be reviewed and approved, in compliance with § 46.101, § 46.102, and § 46.107 through § 46.117 of this policy, by an Institutional Review Board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or Agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or Agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Department or Agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in Department or Agency procedures.

(i) Unless otherwise required by law, Department or Agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the Department or Agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services (DHHS), and shall also publish them in the **Federal Register** or in such other manner as provided in Department or Agency procedures.[1]

[1] Institutions with DHHS-approved assurances on file will abide by provisions

*Continued*

**§ 46.102 Definitions.**

(a) *Department or Agency head* means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or Agency (including Federal, State, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a Federal Department or Agency solely as part of the Department's or Agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an Institutional Review Board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

**§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.**

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency shall provide written assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual Department or Agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, National Institutes Health, DHHS, and approved for Federalwide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to Department and Agency heads shall also be made to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Department or Agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to Department- or Agency-supported or regulated research and need not be

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of Title 45 CFR Part 46 Subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

applicable to any research exempted or waived under § 46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Department or Agency head, unless in accord with § 46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the Department or Agency head prescribes.

(d) The Department or Agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the Department or Agency and such experts or consultants engaged for this purpose as the Department or Agency head determines to be appropriate. The Department or Agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Department or Agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Department or Agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a Federal Department or Agency and not otherwise exempted or waived under § 46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by § 46.103 of this policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the Department or Agency to which the application or proposal is submitted. Under no condition shall research covered by § 46.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the Department or Agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

**§§ 46.104—46.106 [Reserved]**

**§ 46.107 IRB membership.**

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one

member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

**§ 46.108 IRB functions and operations.**

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in § 46.103(b)(4) and to the extent required by § 46.103(b)(5).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

**§ 46.109 IRB review of research.**

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

**§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.**

(a) The Secretary, HHS, has established, and published as a Notice in the **Federal Register**, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the **Federal Register**. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

**§ 46.111 Criteria for IRB approval of research.**

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or



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economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

**§ 46.112 Review by institution.**

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

**§ 46.113 Suspension or termination of IRB approval of research.**

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

**§ 46.114 Cooperative research.**

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

**§ 46.115 IRB records.**

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § 46.103(b)(4) and § 46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

**§ 46.116 General requirements for informed consent.**

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of

records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

**§ 46.117 Documentation of informed consent.**

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

**§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.**

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

**§ 46.119 Research undertaken without the intention of involving human subjects.**

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the Department or Agency, and final approval given to the proposed change by the Department or Agency.

**§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.**

(a) The Department or Agency head will evaluate all applications and proposals involving human subjects submitted to the Department or Agency through such officers and employees of the Department or Agency and such experts and consultants as the Department or Agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the Department or Agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

**§ 46.121 [Reserved]**

**§ 46.122 Use of Federal funds.**

Federal funds administered by a Department or Agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

**§ 46.123 Early termination of research support: Evaluation of applications and proposals.**

(a) The Department or Agency head may require that Department or Agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Department or Agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the Department or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

**§ 46.124 Conditions.**

With respect to any research project or any class of research projects the Department or Agency head may impose additional conditions prior to or at the time of approval when in the judgment of the Department or Agency head additional conditions are necessary for the protection of human subjects.

## Subpart B—Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Source: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978; 43 FR 51559, November 3, 1978.

**§ 46.201 Applicability.**

(a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

**§ 46.202 Purpose.**

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

**§ 46.203 Definitions.**

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services (DHHS) to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of

implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the **Federal Register** guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

**§ 46.204 Ethical Advisory Boards.**

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these Board(s) shall be so selected that the Board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No Board member may be a regular, full-time employee of the Department of Health and Human Services.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

*Nullified June 10, 1993 (Public Law 103-43)*

**§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.**

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) determine that all aspects of the activity meet the requirements of this subpart;

(2) determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

**§ 46.206 General limitations.**

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) appropriate studies on animals and nonpregnant individuals have been completed;

(2) except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;

(3) individuals engaged in the activity will have no part in: (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

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Source: 40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975.

**§ 46.207 Activities directed toward pregnant women as subjects.**

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

**§ 46.208 Activities directed toward fetuses *in utero* as subjects.**

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

**§ 46.209 Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects.**

(a) Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in an activity covered by this subpart unless:

(1) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) vital functions of the fetus will not be artificially maintained,

(2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

**§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.**

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

**§ 46.211 Modification or waiver of specific requirements.**

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the **Federal Register**.

## Subpart C—Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov. 16, 1978.

**§ 46.301 Applicability.**

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

**§ 46.302 Purpose.**

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

**§ 46.303 Definitions.**

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and

any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "DHHS" means the Department of Health and Human Services.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**§ 46.304 Composition of Institutional Review Boards where prisoners are involved.**

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

**§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.**

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

**§ 46.306 Permitted research involving prisoners.**

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) in the judgment of the Secretary the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the **Federal Register,** of his intent to approve such research; or

(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the **Federal Register,** of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or

supported by DHHS shall not involve prisoners as subjects.

## Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983; 56 FR 28032, June 18, 1991.

### § 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at § 46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at § 46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

### § 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

### § 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

### § 46.404 Research not involving greater than minimal risk.

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

### § 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) the risk is justified by the anticipated benefit to the subjects;

(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

### § 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) the risk represents a minor increase over minimal risk;

(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

### § 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

DHHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) the Secretary, after consultation with a panel of experts in pertinent

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disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) the research will be conducted in accordance with sound ethical principles;

(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

**§ 46.408 Requirements for permission by parents or guardians and for assent by children.**

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405. Where research is covered by § 46.406 and § 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

**§ 46.409 Wards.**

(a) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under § 46.406 or § 46.407 only if such research is:

(1) related to their status as wards; or

(2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

## RESEARCH ACTIVITIES WHICH MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

Research activities involving no more than minimal risk *and* in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in § 46.110 of 45 CFR Part 46.

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

**Source:** 46 FR 8392; January 26, 1981.

CITE 20 USC Sec. 1232h
EXPCITE TITLE 20 - EDUCATION
CHAPTER 31 - GENERAL PROVISIONS CONCERNING EDUCATION
SUBCHAPTER III - GENERAL REQUIREMENTS AND CONDITIONS CONCERNING OPERATION AND ADMINISTRATION OF EDUCATION PROGRAMS: GENERAL AUTHORITY OF SECRETARY
Part 4 - Records; Privacy; Limitation on Withholding Federal Funds
HEAD Sec. 1232h. Protection of pupil rights
STATUTE

(a) Inspection of instructional materials by parents or guardians

All instructional materials, including teacher's manuals, films, tapes, or other supplementary material which will be used in connection with any survey, analysis, or evaluation as part of any applicable program shall be available for inspection by the parents or guardians of the children.

(b) Limits on survey, analysis, or evaluations

No student shall be required, as part of any applicable program, to submit to a survey, analysis, or evaluation that reveals information concerning -

(1) political affiliations;
(2) mental and psychological problems potentially embarrassing to the student or his family;
(3) sex behavior and attitudes;
(4) illegal, anti-social, self-incriminating and demeaning behavior;
(5) critical appraisals of other individuals with whom respondents have close family relationships;
(6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or
(7) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program), without the prior consent of the student (if the student is an adult or emancipated minor), or in the case of an unemancipated minor, without the prior written consent of the parent.

(c) Notice

Educational agencies and institutions shall give parents and students effective notice of their rights under this section.

(d) Enforcement

The Secretary shall take such action as the Secretary determines appropriate to enforce this section, except that action to terminate assistance provided under an applicable program shall be taken only if the Secretary determines that -

(1) there has been a failure to comply with such section; and
(2) compliance with such section cannot be secured by voluntary means.

(e) Office and review board

The Secretary shall establish or designate an office and review board within the Department of Education to investigate, process, review, and adjudicate violations of the rights established under this section.

SOURCE (Pub. L. 90-247, title IV, Sec. 445, formerly Sec. 439, as added Pub. L. 93-380, title V, Sec. 514(a), Aug. 21, 1974, 88 Stat. 574; amended Pub. L. 95-561, title XII, Sec. 1250, Nov. 1, 1978, 92 Stat. 2355; Pub. L. 103-227, title X, Sec. 1017, Mar. 31, 1994, 108 Stat. 268; renumbered Sec. 445, Pub. L. 103-382, title II, Sec. 212(b)(1), Oct. 20, 1994, 108 Stat. 3913.)

MISC1 PRIOR PROVISIONS

A prior section 445 of Pub. L. 90-247 was classified to section 1233d of this title prior to repeal by Pub. L. 103-382.

AMENDMENTS

1994 - Pub. L. 103-227 amended section generally, substituting in subsec. (a), provisions relating to inspection of instructional materials by parents or guardians for similar provisions, in subsec. (b), provisions relating to limits on survey, analysis, or evaluations for provisions relating to psychiatric or psychological examinations, testing, or treatment, and adding subsecs. (c) to (e).

1978 - Pub. L. 95-561 designated existing provisions as subsec. (a) and added subsec. (b).

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-561 effective Oct. 1, 1978, see section 1530(a) of Pub. L. 95-561, set out as a note under section 1221e-3 of this title.

EFFECTIVE DATE

Section 514(b) of Pub. L. 93-380 provided that: "The amendment made by subsection (a) (enacting this section) shall be effective upon enactment of this Act (Aug. 21, 1974)."

HR 1271

AN ACT

To provide protection for family privacy.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Family Privacy Protection Act of 1995'.

SEC. 2. FAMILY PRIVACY PROTECTION.

(a) Restriction on Seeking Information From Minors: Notwithstanding any other provision of law and subject to section 6, in conducting a program or activity funded in whole or in part by the Federal Government a person may not, without the prior written consent of at least one parent or guardian of a minor or, in the case of an emancipated minor, the prior consent of the minor, require or otherwise seek the response of the minor to a survey or questionnaire which is intended to elicit, or has the effect of eliciting, information concerning any of the following:

(1) Parental political affiliations or beliefs.
(2) Mental or psychological problems.
(3) Sexual behavior or attitudes.
(4) Illegal, antisocial, or self-incriminating behavior.
(5) Appraisals of other individuals with whom the minor has a familial relationship.
(6) Relationships that are legally recognized as privileged, including those with lawyers, physicians, and members of the clergy.
(7) Religious affiliations or beliefs.

(b) General Exceptions: Subsection (a) shall not apply to any of the following:

(1) The seeking of information for the purpose of a criminal investigation or adjudication.
(2) Any inquiry made pursuant to a good faith concern for the health, safety, or welfare of an individual minor.
(3) Administration of the immigration, internal revenue, or customs laws of the United States.
(4) The seeking of any information required by law to determine eligibility for participation in a program or for receiving financial assistance.

(c) Academic Performance Tests: Subsection (a) shall not apply to tests intended to measure academic performance except to the extentthat questions in such tests would require a minor to reveal information listed in a paragraph of subsection (a).

SEC. 3. NOTIFICATION PROCEDURES.

The head of any Federal department or agency which provides funds for any program or activity involving the seeking of any response from a minor to any survey or questionnaire shall establish procedures by which the department, agency, or its grantees shall notify minors and their parents of protections provided under this Act. The procedures shall also provide for advance public availability of each questionnaire or survey to which a response from a minor is sought.

SEC. 4. COMPLIANCE.

The head of each Federal department or agency shall establish such procedures as are necessary to ensure compliance with this Act and the privacy of information obtained pursuant to this Act by the department or agency and its grantees. Nothing in this Act shall be construed to foreclose any individual from obtaining judicial relief.

SEC. 5. MINOR DEFINED.

In this Act, the terms `minor' and `emancipated minor' will be defined under the laws of the State in which the individual resides.

SEC. 6. APPLICATION.

This Act does not apply to any program or activity which is subject to the General Education Provisions Act (20 U.S.C. 1221 et seq.).

SEC. 7. EFFECTIVE DATE.

This Act shall take effect 90 days after the date of the enactment of this Act.

Passed the House of Representatives April 4, 1995.
104th Congress
1st Session

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| CONGRESS: | 104 |
| BILL NO: | H.R. 1271 |
| OFFICIAL TITLE: | A bill to provide protection for family privacy |
| SPONSOR: | Horn |
| DATE INTRODUCED: | 03-21-95 |
| BRIEF TITLE: | Family Privacy Protection Act of 1995 |

COSPONSORS: 14 CURRENT COSPONSORS

| | |
|---|---|
| As Introduced | Clinger, Bass, Blute, Davis, Flanagan, Fox, Scarborough, Tate. |
| 03-23-95 | Gilman, Burton, Shays, Zeliff, Shadegg, Martini. |

COMMITTEE/SUBCOMMITTEE REFERRAL:

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|---|---|
| 03-21-95 | House Committee on Government Reform and Oversight. |
| 04-05-95 | Senate Committee on Governmental Affairs. |

VOTE TOTAL OUT OF HOUSE COMMITTEE:

| | |
|---|---|
| 03-23-95 | Ordered to be Reported by House Committee on Government Reform. Voice Vote. (Favorably) |

LEGISLATIVE ACTION:

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| 03-21-95 | Referred to House Committee on Government Reform and Oversight. |
| 03-23-95 | Referred to Subcommittee on Government Management, Information and Technology. |
| 03-23-95 | Subcommittee on Government Management, Information and Technology Discharged. |
| 03-23-95 | Committee Consideration and Mark-up Session Held. |
| 03-23-95 | Ordered to be Reported (Amended) by Voice Vote. |
| 03-29-95 | Reported to House (Amended) by House Committee on Government Reform and Oversight Report No: 104-94. |
| 03-29-95 | Placed on Union Calendar No: 45. |
| 04-03-95 | Committee on Rules Granted an Open Rule Providing for One Hour of General Debate. |
| 04-03-95 | Rules Committee Resolution H. Res. 125 Reported to House. |
| 04-04-95 | Rule Passed House. |
| 04-04-95 | Called up by House by Rule. |
| 04-04-95 | Committee Amendment in the Nature of a Substitute Considered as an Original Bill for the Purpose of Amendment. |
| 04-04-95 | House Agreed to Amendments Adopted by the Committee of the Whole. |
| 04-04-95 | Passed House (Amended) by Recorded Vote: 418 - 7 (Record Vote No: 287). |
| 04-05-95 | Received in the Senate. |
| 04-05-95 | Referred to Senate Committee on Governmental Affairs. |
| 11-09-95 | Committee on Governmental Affairs. Hearings held. |

AMENDMENTS: This Bill has
2 HOUSE AMENDMENTS

Souder 04-04-95 HA 335 (A001 - Passed)
An amendment consisting of several amendments, offered en bloc, to require that the prior parental consent provisions in the bill for student participation in any federally sponsored survey or questionaire be in writing; to require such consent for any survey or questionaire that has the effect of eliciting sensitive information, regardless of its specified purpose; to exempt academic tests, if the test questions do not request sensitive information; and remove the $500 limit on monetary damages that an individual may claim for a violation of the provisions of the bill.

Dornan 04-04-95 HA 336 (A002 - Failed)
No Description Available

COMMITTEE/CONFERENCE REPORT NUMBERS:
03-29-95 Reported (Amended) by the Committee on Government Reform. H. Rept. 104-94.

RELATED LEGISLATION:
CLERK
H.Res. 125

CONGRESSIONAL RECORD PAGE REFERENCE:

| | | |
|---|---|---|
| 03-23-95 | H3733 | Cosponsors added |
| 03-29-95 | H3974 | Reported with amendment (H. Rept. 104-94) |
| 04-03-95 | H4104 | Mades special order (H. Res. 125) |
| 04-04-95 | H4129 | Debated |
| 04-04-95 | H4137 | Debated |
| 04-04-95 | H4137 | Amendments |
| 04-04-95 | H4141 | Amended and passed House |
| 04-05-95 | S5217 | Referred to the Committee on Governmental Affairs |
| 03-21-95 | H3416 | Introductory information |

BILL DIGEST (Rev) Apr 4, 95.

(Passed House, amended )

Family Privacy Protection Act of 1995 - Declares that in conducting a program or activity funded in whole or in part by the Federal Government a person may not, without prior written parental or guardian consent (or, if the minor is emancipated, without the minor`s own prior consent), require or otherwise seek the response of the minor to a survey or questionnaire intended to elicit, or having the effect of eliciting, information concerning: (1) parental political affiliations or beliefs; (2) mental or psychological problems; (3) sexual behavior or attitudes; (4) illegal, anti-social, or self-incriminating behavior; (5) appraisals of other individuals with whom the minor has a familial relationship; (6) relationships legally recognized as privileged, such as those with lawyers, physicians, and clergy; or (7) religious affiliations or beliefs.

Exempts from this prohibition: (1) the seeking of information for the purpose of a criminal investigation or adjudication; (2) any inquiry made pursuant to a good faith concern for the health, safety, or welfare of an individual minor; (3) administration of the immigration, internal revenue, or customs laws of the United States; or (4) the seeking of any information required by law to determine eligibility for participation in a program or for receiving financial assistance.

Exempts from such prohibition as well any tests intended to measure academic performance except to the extent that questions in such tests would require a minor to reveal information proscribed by this Act.

Prescribes agency notice and compliance requirements.

States that this Act does not apply to any program or activity which is subject to the General Education Provisions Act.

Felice Levine testifies on Family Privacy Protection Act

Social psychologist Felice J. Levine, Ph.D., executive officer of the American Sociological Association, testified before the Senate Committee on Governmental Affairs on the Family Privacy Protection Act on Nov. 9, 1995. She spoke on behalf of the Research and Privacy Coalition, of which APA is a member.

Testimony of
Felice J. Levine, Ph.D.
Executive Officer
American Sociological Association
on behalf of
The Research and Privacy Coalition
before the
Senate Committee on Governmental Affairs
The Honorable Ted Stevens, Chair
Washington, D.C.
November 9, 1995

INTRODUCTION

Mr. Chairman, thank you for the opportunity to come before your committee to discuss an issue of great importance to American youth and their families. I am Dr. Felice Levine, Executive Officer of the American Sociological Association. Trained as a social psychologist, I conducted research on children and youth, and spent twelve years as a Program Director at the National Science Foundation. In that context, I worked on such issues as human subjects protection, privacy, and confidentiality of data.

Today, I am here on behalf of the Research and Privacy Coalition, to testify in opposition to H.R. 1271, "The Family Privacy Protection Act of 1995." As indicated in the attachment, our coalition is comprised of a diverse group of organizations that represent parents, researchers, health care providers, educators, child advocates, and community groups dedicated to improving the health and quality of life of young Americans and their parents. Our organizations strongly support informed parental consent. However, we are deeply concerned about the negative effects of H.R. 1271 on parents, children, and the nation's ability to monitor, understand, and address crucial problems among its youth. These concerns force us to oppose this legislation.

H.R. 1271 ostensibly enhances parental involvement and control over questions or information directed to a minor, but the bill actually

undermines critical research on youth health behaviors and provides no significant additional protection to the privacy of families. Ironically, while this bill purports to help parents, it is more likely to harm their interests by jeopardizing their access to essential and valid information on high risk health behaviors such as drug and alcohol use, tobacco use, violence, and the like.

Before discussing the specific reasons our coalition opposes H.R. 1271, I will summarize briefly the legislative history of this bill.

History of Legislation

The roots of this proposed legislation originate in 1968 with the General Education Provisions Act (GEPA). GEPA, originally enacted as Title IV of the Elementary and Secondary Education Amendments of 1967, brought together in one document statutory provisions enacted during the previous 100 years that applied to federal education programs. Since 1970, most major acts extending Federal education programs' authorization for appropriations have amended GEPA in some significant way. Three of those changes (the "Kemp amendment," 1974; the "Hatch amendment," 1978; and the "Grassley amendment," 1994) have significantly affected the "Protection of Pupils" section of GEPA.

The Kemp amendment required that parents of pupils participating in federally-assisted research projects be provided access to the relevant instructional materials. The Hatch amendment enhanced pupil protection by requiring prior consent of the pupil (if an adult or emancipated minor) or the pupil's parent/guardian and referred to specific areas of inquiry such as political affiliations; mental or psychological problems; sexual behavior or attitudes; illegal, antisocial, or "demeaning" behavior; "critical appraisals" of family members; privileged relationships; or income. The Grassley amendment expanded consent requirements to "any survey, analysis, or evaluation" that was federally-assisted, contained a lower threshold for triggering the consent requirements, and mandated written parental consent. The impact of these amendments was limited to federally-assisted programs funded by the Department of Education.

H.R. 1271, "The Family Privacy Protection Act of 1995," extends the jurisdiction of the 1994 Grassley amendment to all federally-funded government programs, and was originally introduced in the House as Title IV of H.R. 11, "The Family Reinforcement Act." It was referred to the Committee on Government Reform and Oversight. The Subcommittee on Government Management, Information, and Technology held a hearing on March 16, 1995, and Senator Charles Grassley of Iowa, Dr. Lloyd Johnston of the University of Michigan, Dr. Matthew Hilton of Utah, Ms. Sally Katzen of the

Office of Management and Budget (OMB), and Mr. William T. Butz of the Bureau of the Census testified.

As a result of this testimony, Subcommittee Chairman Stephen Horn of California introduced an amendment in the form of a substitute to H.R. 11, and this amendment was introduced as H.R. 1271, "The Family Privacy Protection Act of 1995," on March 21, 1995. The provisions in this revised legislation include the requirement that active consent from a parent/guardian is required. The consent can be handled in various ways, including in writing. The mere notice of a survey is not enough to satisfy the consent requirement; there is a two-tier test necessary for consent. First, the parent/guardian needs to have disclosure about the survey or questionnaire. Second, the parent/guardian must have an opportunity to decline and notification must include a readily accessible method for the parent/guardian to exercise this option to decline. The legislation passed the Subcommittee unanimously by voice vote. The bill was marked-up by the subcommittee on March 22, 1995.

The Government Reform and Oversight Committee met on March 23, 1995 to consider H.R. 1271. The bill as amended by the Subcommittee was favorably reported to the House unanimously by voice vote. We believe that the bill reported to the House by the Subcommittee and subsequently by the Committee was a fair and reasonable bill, accommodating concerns expressed by federal agencies researchers, parents, and private citizens.

On April 4, 1995 as the full House considered H.R. 1271, Rep. Mark Souder of Indiana sponsored an amendment which reinstated an absolute requirement for written parental consent for participation of a minor. The House approved the legislation with this amendment, despite the unanimous recommendations from the Subcommittee and the Committee against an inflexible requirement of written consent from parents.

## Concerns and Recommendations

Our concerns with H.R. 1271 are as follows:

1. H.R. 1271 assumes that a significant number of parents will object to the participation of their children in federally sponsored survey research. We know of no data to support that assumption; in fact, the reverse is the case. In follow-up studies with parents who did not initially respond to a request for written permission, the overwhelming majority gave their consent for their children to participate. The same study showed that human nature to procrastinate, and not active refusal to participate, was the major reason parents did not return the permission forms.

We urge the Committee to recognize that the vast majority of parents–including those who do not initially respond–support their children's participation in survey research.

2. H.R. 1271 proposes a single mechanism for obtaining parental consent, thereby denying the opportunity to use more effective procedures. The bill requires a written statement from parents before a federally-funded survey or questionnaire may be given to a minor. This is not always the best way to ensure that parents are fully informed of the benefits and risks involved in their child's participation in a research survey. For example, a face-to-face interview or a telephone call might be more appropriate, especially when parents are illiterate or less likely to understand the rights they have under current human subject protection rules.

   The current standard used by the federal government is that "informed consent" must be obtained. We strongly affirm that Congress must emphasize "informed" and leave the specific means by which consent is obtained to fit the specific purposes of, and population in, any proposed study.

   We suggest that decisions regarding the most appropriate means to obtain parental permission for the participation of minors in federally-sponsored surveys require case-by-case attention to situation and local circumstances–with federal agencies, Institutional Review Boards, and researchers held accountable for responsible implementation.

   Unfortunately the public is not sufficiently aware of the stringent procedures in place for federally supported research with regard to protection of human subjects. It may be useful at this point to review these procedures.

   Federal guidelines and regulations (45 CFR 46) are working to assure that research subjects are informed of any risks and benefits of proposed research, and that they are given sufficient information about the research to decide whether to participate. The regulations specifically address the involvement of parents or guardians in research with children. Any proposed research project conducted by federal grantees must be reviewed and approved by official Institutional Review Boards (IRBs) whose deliberations must consider such issues as consent, privacy, confidentiality, benefits, and risks. IRBs exist solely for the purpose of protecting the rights of all human subjects of research. These review boards include public members.

Research proposals must pass IRB review in order to be funded by a federal agency. IRBs, as well as the regular peer review process at the federal agency, are designed to ensure that a research plan involving young subjects includes a method to inform potential subjects and their parents about the study, and to obtain informed consent to the subject's participation. Reviewers require the researcher to have in place procedures assuring confidentiality and anonymity of respondents. Finally, every person who is asked to be a subject in a federally funded study has the right, and is given the opportunity, to decline to participate.

Who are the people who serve on these boards? The Regulations for the Protection of Human Subjects of Research established requirements concerning the membership of a local IRB, including: "each IRB shall have at least five members, with varying backgrounds. . . ;" it "shall be sufficiently qualified through. . . the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects;" if it "regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects;" "each IRB shall include at least one member whose primary concerns are in. . . nonscientific areas;" and "each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." As is apparent, these federal regulations have recognized the necessity for research to be sensitive to local standards of acceptability, particularly when studies involve special vulnerable populations such as children.

In 1991, the sixteen federal agencies that conduct, support, or otherwise regulate human subjects research, adopted the Federal Policy for the Protection of Human Subjects, or the "Common Rule," as it is sometimes called. The virtually government-wide adoption of the Federal Policy made uniform the human subjects protection system in all relevant federal departments and agencies. Unfortunately, several key provisions of H.R. 1271 are inconsistent with the basic principles of the Federal Policy, which for over two decades have been strengthened and enhanced to better ensure a model system for the ethical participation of human subjects in research.

3. H.R. 1271 ignores the rights of children to assent or decline to

answer a federal survey or questionnaire. Current human subject rules protect subjects from participating in any federal research against their will. It is important that children know they can refuse participation, free of social pressure or even subtle coercion.

We suggest that a bill protecting the privacy and rights of parents should also protect the privacy and rights of children.

4. H.R. 1271 flies in the face of this Committee's efforts via the Paperwork Reduction Act to decrease unnecessary paperwork throughout the government. It will mandate data collection burdens on parents, schools, and researchers that are unnecessary and costly without consideration of what is really appropriate and efficient. In school-based research, for example, the repeated follow-up contacts, the added notices, the multiple mailings, impose substantial human and material costs, without the provision of resources to implement this requirement.

   The added costs are an issue this Committee must consider. Studies have shown that only about half of parents, at most, will respond to an initial note requesting written permission for a child to participate in a federal survey. Repeated follow-ups are necessary to achieve an acceptable rate of return of signed consent forms. A study by the Rand Corporation showed that the cost to achieve written consent for a single subject ranges from a low of $25.00 to a high of nearly $50.00. The cost of follow up just to obtain signed consent forms for a reasonably large study involving, say, 4,000 subjects, could add more than $100,000 to the cost of a study. To give some idea how to measure the import of that figure, consider that the average grant from the National Science Foundation for behavioral or social science research is about $50,000. An NSF grant likely could not cover the costs just of getting the consent forms returned, let alone doing the actual research and carrying out the subsequent analysis. Large national studies could disappear.

   We request that an analysis of the costs and bureaucratic burdens that H.R. 1271 will impose on parents, schools, and researchers be undertaken in assessing whether such legislation is appropriate.

5. H.R. 1271 will have a serious negative impact on the quality of research findings involving minors. Because of the low initial response rate of parents in returning written permission statements, an absolute federal mandate requiring written permission from parents will result in insufficient sample sizes, thereby invalidating research findings. Studies of those who fail to respond to requests

for written consent indicate that there is an over-representation among non-respondents of members of minority groups, low achievers, children with less well-educated parents, and most importantly, those at risk for engaging in problem behaviors. No study that excluded those children could claim to track accurately the health-damaging or health-enhancing behaviors of any community's young people. Simply put, with reduced sample size and biased responses, the federal government will not be able to meet its responsibility for informing the public about endemic problems.

We recommend that the Committee weigh the importance of having valid data to inform policy decisions regarding minors and assess the detrimental impact of this loss in knowledge.

6. H.R. 1271 will especially harm our ability to know how to help minors who engage in high risk behaviors like smoking, drug abuse, and violence. Given that research has shown that children whose parents do not return parental consent forms are at a higher risk for health and social problems, we must ask: Who is H.R. 1271 likely to hurt? Ultimately, it will hurt the children whose pediatricians may not know of the emergence of a new drug of abuse, the children whose community policemen may not know how to spot the kids most at risk for gang membership, and the children whose parents will not know how early to discuss problem drinking with them. The survey research that H.R. 1271 would stifle or render ineffective is now relied on by policy makers, health care providers, parents, law enforcement officials, and all of us who care about children and youth.

   We urge the Committee to protect these important sources of information that enable you, and our communities, to do what is right for our children. As the Committee deliberates on this bill, we respectfully ask you to consider the harmful effects of crippling our nation's capacity to protect the most vulnerable among us–our children and youth.

## CONCLUSION

In conclusion, let me emphasize that a win-win solution is both feasible and desirable. We share the interest of concerned legislators in fully informed parental consent, children's assent, and useful and meaningful information. We know that parental permission can be obtained without damaging the viability of scientific questionnaires and surveys. These goals are not mutually exclusive. A bill can be crafted that strengthens parental consent without imposing a single Congressional solution to a process that demands multiple approaches, flexibility, and judgment. In the

coming weeks, your Committee will have the opportunity to amend the Family Privacy Protection Act. We appreciate the attention you are giving to this issue and are eager to assist in any way we can.